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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/465,925	12/17/99	RUSSI J	2124-314

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EXAMINER

WANG, A

ART UNIT

PAPER NUMBER

1635

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DATE MAILED: 09/18/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/465,925

Applicant(s)

ROSSI ET AL.

Examiner

Andrew Wang

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) ____ is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claims ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

KATRINA TURNER
PATENT ANALYST

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 18) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

DETAILED ACTION***Response to Arguments***

1. Claims 1-9 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-19 of U.S. Patent No. 5,827,935. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instantly claimed methods of colocalizing modified ribozymes would embrace the modified ribozymes as claimed in '935.

Applicants have stated that a terminal disclaimer will be filed upon indication of allowable subject matter. No further arguments were provided.

2. Rejection of claims 1-9 under 35 U.S.C. 102(a) as being anticipated by Sullenger et al. (Science) is hereby withdrawn in view of applicants newly claimed priority.

3. Rejection of claims 1-9 under 35 U.S.C. 102(e) as being anticipated by US Patent No. 5,854,038 ('038) is hereby withdrawn in view of applicants newly claimed priority.

4. Claims 1, 3-5, 8, and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Sullenger et al. (Cell) for the same reasons of record as set forth in the Office action mailed 8 January 2001.

Applicant's arguments filed 9 July 2001 have been fully considered but they are not persuasive. Applicants argue that Sullenger does not teach co-localization to lead to increased concentration of the inhibitor but contrary to applicants assertions Sullenger cites the works of others teaching the colocalization. Furthermore, applicants assertion that the work of others is nothing but speculation is unfounded since applicants have not provided any evidence or reasoning to contradict said observation. Moreover, Sullenger does in fact teach the use as ribozymes as an inhibitor, although not specifically exemplified. Sullenger clearly teaches that a high level of ribozyme transcription is required for effective inhibition (page 601, second paragraph) and demonstrates that the tRNA^{met} was capable of said high transcription of an inhibitor, particularly TAR.

5. Claims 1-9 are rejected under 35 U.S.C. 112, first paragraph, because the specification is only enabling for claims limited to a method of colocalizing an inhibitory agent comprising a localization signal in cells, in vitro. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims for the same reasons of record as set forth in the Office action mailed 8 January 2001.

Applicant's arguments filed 9 July 2001 have been fully considered but they are not persuasive. Applicants argue that the cited references do not provide any doubt regarding the in vivo use of the claimed construct but rather provide for encouraging uses of the of the described technologies. Although many in vivo studies have been performed as cited by Agrawal, such studies cannot be generically applied to all disease

conditions as was clearly stated by Agrawal. Agrawal clearly states that many parameters must be considered in using oligonucleotides for therapy, as noted in the prior Office action. In considering said parameters, the skilled artisan would clearly have to engage in trial and error experimentation to successfully use the instantly claimed methods in vivo. Furthermore, Gewirtz, although citing clinical trials, clearly notes that the oligo therapy is still considered unpredictable since the target's structure and target cell delivery needs to be determined. Moreover, Branch supports the unpredictability of oligo therapy as set forth by both Agrawal and Gewirtz by noting that oligo therapy needs to be considered on a case-by-case basis for successful therapy application. Thus, based on the state of the art at the time of the invention and the disclosure the skilled artisan would have to engage in undue trial and error experimentation to resolve the difficulties associated with the in vivo application of the disclosed compositions, as taught by the cited art, thereby not adequately enabling the skilled artisan to practice the invention as claimed.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

Art Unit: 1635

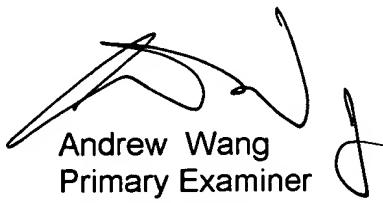
extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew Wang whose telephone number is 703-306-3217. The examiner can normally be reached on Monday thru Thursday, 6:30 a.m.-5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on 703-308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

AJW
September 18, 2001


Andrew Wang
Primary Examiner
Art Unit 1635